SPINRAZA®
(nusinersen) injection
12 mg/5 mL

GUIDE TO REAUTHORIZATION
(RENEWAL OF AUTHORIZATION)

INDICATION
SPINRAZA® (nusinersen) is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

SELECTED IMPORTANT SAFETY INFORMATION
Coagulation abnormalities and thrombocytopenia, including acute severe thrombocytopenia, have been observed after administration of some antisense oligonucleotides. Patients may be at increased risk of bleeding complications.

In the sham-controlled studies for patients with infantile-onset and later-onset SMA, 24 of 146 SPINRAZA-treated patients (16%) with high, normal, or unknown platelet count at baseline developed a platelet level below the lower limit of normal, compared to 10 of 72 sham-controlled patients (14%). Two SPINRAZA-treated patients developed platelet counts <50,000 cells per microliter, with the lowest level of 10,000 cells per microliter recorded on study day 28.

Please see additional Important Safety Information on page 6 and accompanying full Prescribing Information.

GUIDE TO REAUTHORIZATION FOR SPINRAZA® (nusinersen)

UNDERSTANDING THE NEED FOR REAUTHORIZATIONS

For many drugs that treat rare diseases, health plans may require an authorization renewal after a certain period. For SPINRAZA, this period is typically every 6 months or every year. Obtaining reauthorization is necessary to ensure that the patient will continue to receive coverage and remain on treatment.

For patients continuing on therapy, health plans have different approval periods (durations of coverage)

It is important to become familiar with the medical policy for SPINRAZA for each patient's health plan

Be mindful of the duration of coverage for the initial treatment authorization and the patient's start date

You can find out the medical policy of your patients' health plans by visiting the health plan websites or by contacting your Biogen representative. After you determine the policy, you can record it on the **Health Plan Reference Sheet**, available at **spinraza-hcp.com**.

Timing is everything. If possible, start preparing documents several months before reauthorization is needed. Set a reauthorization target date.

SMA360™
Support services from Biogen

Biogen can help your practice or facility understand the reauthorization requirements for individual health plans in your area. Call SMA360° at **1-844-4SPINRAZA (1-844-477-4672)**, Monday through Friday, 8:30 AM to 8:00 PM ET, or contact your Biogen representative.

SELECTED IMPORTANT SAFETY INFORMATION

Renal toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. SPINRAZA is present in and excreted by the kidney. In the sham-controlled studies for patients with infantile-onset and later-onset SMA, 71 of 123 SPINRAZA-treated patients (58%) had elevated urine protein, compared to 22 of 65 sham-controlled patients (34%).

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THE DOSING SCHEDULE FOR SPINRAZA: IMPLICATIONS FOR REAUTHORIZATION

It is a good practice to keep in mind the dosing schedule for SPINRAZA—and the patient's start date—to help avoid a treatment interruption. It serves as a reminder to prepare the documents necessary for reauthorization early.

- Patients treated with SPINRAZA receive a loading dose on approximately days 0, 14, 28, and 58, and a maintenance dose every 4 months thereafter[1]

If reauthorization is not obtained in time:

- For plans requiring renewal **every 6 months**: initial approval coverage may end before maintenance dosing begins
- For plans requiring renewal **every 12 months**: initial approval coverage may end while patient is between maintenance doses

Consider the time it will take for reauthorization of SPINRAZA when planning maintenance dosing.

WHAT INFORMATION DO HEALTH PLANS REQUIRE FOR REAUTHORIZATION OF SPINRAZA?

For reauthorization, it is important to show that patients on SPINRAZA had a clinically significant treatment response. Treatment response for a patient on SPINRAZA can take the form of an improvement in physical functioning, maintenance of an existing level of functioning, or a slowing of functional decline. Treatment responses can differ depending on the patient and his or her age, disease severity, and treatment goals.[1,2]

- Achieving motor milestones may be important for pediatric patients
- Maintaining (or slowing decline in) motor milestones that have already been achieved may be important for adult patients
- **Remember, even the smallest change in a functional assessment score or maintenance of an activity of daily living could be critical to include as documentation for the reauthorization of SPINRAZA**

Ensure a baseline assessment is done and then document changes in (or maintenance of) motor milestones at every patient visit, so you can provide evidence of SPINRAZA efficacy to the patient's health plan.

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

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GUIDE TO REAUTHORIZATION FOR SPINRAZA® (nusinersen) (*cont'd*)

DOCUMENTING FUNCTIONAL IMPROVEMENTS TO SUPPORT REAUTHORIZATION

Health plan medical policies generally specify the types of functional assessments they require for reauthorization of SPINRAZA. The following motor milestone assessments may be appropriate to use when evaluating a patient's outcomes with SPINRAZA. They can be beneficial for documenting an improvement in motor milestones or demonstrating that existing motor milestones have not been lost.

- The Hammersmith Infant Neurological Examination (HINE) Section 2
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM)
- Six-Minute Walk Test (6MWT)
- World Health Organization (WHO) Motor Milestones

Note: Not all of the assessments above will be relevant to every patient or health plan.

In addition to these assessments, it is important to document and submit any additional measurements that could be better indicators of a patient's response to SPINRAZA therapy and help build the case for reauthorization. These could include self-care activities of daily living (such as personal hygiene and feeding) or mobility-related activities (such as working, operating a wheelchair, grocery shopping, and attending doctor appointments). It is also beneficial to include the prescriber's feedback regarding the patient's outcome with SPINRAZA.

If a reauthorization request is denied, determine the necessary steps to submit an appeal, which could include a letter of medical necessity.

THE PROCESS FOR REAUTHORIZATION

The process for requesting a reauthorization for SPINRAZA treatment will vary depending on the patient's health plan.

- Contact the health plan to find out the specific requirements for reauthorization, such as required forms. Reference the health plan's most current medical policy for SPINRAZA
- Determine the supporting documentation that may be required, such as patient notes and results of functional assessments

Procurement is a key factor. Consider the time it takes to procure SPINRAZA and ensure that the reauthorization process is completed with ample time to obtain the product.

SELECTED IMPORTANT SAFETY INFORMATION

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

Cases of rash were reported in patients treated with SPINRAZA.

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IF REAUTHORIZATION IS DENIED, THE NEXT STEP IS TO FILE AN APPEAL

In the case of a denial, it will be necessary to submit an appeal, which may include a letter of medical necessity and other supporting documentation. The following is a summary of the basic steps for submitting an appeal.

Step 1: Understand the reason for the denial

- Read the letter from the health plan (explanation of benefits) to identify the reason that treatment was denied
- Contact the health plan with any questions and to find a way to quickly resolve the matter
- One of the main reasons that authorization requests are denied is incomplete or inaccurate information on the form

Step 2: Appeal the denial

- Follow the health plan's guidelines and timeframes. Obtain a written description of its appeals process
- Complete the health plan's appeal request form. Forms are usually available at the health plan's website
- Use the **Letter of Medical Necessity/Appeal Template for SPINRAZA**, available at **spinraza-hcp.com**, for support and information you may want to include with the appeal request
- Provide additional documentation to clinically justify the use of SPINRAZA and strengthen the appeal request
- Contact the health plan directly to have a peer-to-peer discussion. This may help the health plan to better understand your treatment decision

Step 3: Monitor the appeal

- Follow up with the health plan to confirm that your request was received and to check the status of its decision
- Notify the patient of instances for which your office may need his or her involvement

For more information about appealing a coverage decision, refer to the Guide to Requesting Medical Exceptions and Appealing Denials, available at spinraza-hcp.com.

SELECTED IMPORTANT SAFETY INFORMATION

SPINRAZA may cause a reduction in growth as measured by height when administered to infants, as suggested by observations from the controlled study. It is unknown whether any effect of SPINRAZA on growth would be reversible with cessation of treatment.

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The most common adverse reactions (≥20% of SPINRAZA-treated patients and ≥5% more frequently than in control patients) that occurred in the infantile-onset controlled study were lower respiratory infection and constipation. Serious adverse reactions of atelectasis were more frequent in SPINRAZA-treated patients (18%) than in control patients (10%). Because patients in this controlled study were infants, adverse reactions that are verbally reported could not be assessed. The most common adverse reactions that occurred in the later-onset controlled study were pyrexia, headache, vomiting, and back pain. Post-lumbar puncture syndrome has also been observed after the administration of SPINRAZA.

Please see accompanying full Prescribing Information.

References: 1. SPINRAZA [Prescribing Information]. Cambridge, MA: Biogen. **2.** Mercuri E, Darras BT, Chiriboga CA, et al; for the CHERISH Study Group. Nusinersen versus sham control in later-onset spinal muscular atrophy. *N Engl J Med*. 2018;378(7):625-635.

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